

may aid in the diagnosis of certain thyroid disorders, such as Hashimoto's disease (chronic lymphocytic thyroiditis), nontoxic goiter (enlargement of thyroid gland), Grave's disease (enlargement of the thyroid gland with protrusion of the eyeballs), and cancer of the thyroid.

(b) *Classification*. Class II (performance standards).

§ 866.5880 Transferrin immunological test system.

(a) *Identification*. A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and other body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

(b) *Classification*. Class II (performance standards).

§ 866.5890 Inter- α trypsin inhibitor immunological test system.

(a) *Identification*. An inter- α trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the inter- α trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter- α trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 53 FR 11253, Apr. 6, 1988; 65 FR 2313, Jan. 14, 2000]

§ 866.5900 Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.

(a) *Identification*. The CFTR gene mutation detection system is a device used to simultaneously detect and identify a panel of mutations and variants in the CFTR gene. It is intended as an aid in confirmatory diag-

nostic testing of individuals with suspected cystic fibrosis (CF), carrier identification, and newborn screening. This device is not intended for stand-alone diagnostic purposes, prenatal diagnostic, pre-implantation, or population screening.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: CFTR Gene Mutation Detection System." See § 866.1(e) for the availability of this guidance document.

[70 FR 61738, Oct. 26, 2005]

§ 866.5910 Quality control material for cystic fibrosis nucleic acid assays.

(a) *Identification*. Quality control material for cystic fibrosis nucleic acid assays. A quality control material for cystic fibrosis nucleic acid assays is a device intended to help monitor reliability of a test system by detecting analytical deviations such as those that may arise from reagent or instrument variation in genetic testing. This type of device includes recombinant, synthetic, and cell line-based DNA controls.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays." See § 866.1(e) for the availability of this guidance document.

[72 FR 1176, Jan. 10, 2007]

Subpart G—Tumor Associated Antigen immunological Test Systems

§ 866.6010 Tumor-associated antigen immunological test system.

(a) *Identification*. A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.